

National Pirogov Memorial Medical University, Vinnytsia

"APPROVE"

Higher Educational Institution
Vice-Rector for Scientific and
Academic Work and International Links

Inna ANDRUSHKO

"30" August 2024 year

«AGREED»

Head of the Department of Pharmacy
[Signature] Olena KRYVOVIAZ

"30" August 2024 year

SYLLABUS
of academic discipline

PROCEEDING PRACTICE ON DRUG TECHNOLOGY

Specialty	226 Pharmacy, Industrial Pharmacy
Specialization	226.01 Pharmacy
Educational level	the second (master's) level
Educational programme	<i>EPP «Pharmacy», 2023</i>
Academic year	2024-2025
Department	Pharmacy
Lecturer (if lectures are given)	Ass. Prof. of HEI Tetiana VOITENKO
Contact information	<i>pharmacy@vnmnu.edu.ua</i>
Syllabus compiler	Ass. Prof. of HEI Tetiana VOITENKO

1. Status and structure of the discipline

Discipline status	Compulsory
Discipline code in EPP/ discipline place in EPP	SC 49 / discipline of professional training
Course / semester	4th year (8 semester)
The amount of discipline (the total number of hours / number of credits ECTS)	75 hours / 2,5 credits ECTS
Number of content modules	-
The structure of the discipline	Lectures - _0_ hours Practical classes _0_ hours Independent work _75_ hours
Language of study	English
Form of study	Full-time (or distance according to the order)

2. Description of the discipline

The main focus of the programme is the acquisition of theoretical knowledge and practical skills in drug technology, the study of which is necessary for the successful mastery of professional training disciplines. The subject area of the programme is the theoretical aspects of technological processes in the manufacture of medicines in pharmacies and industrial pharmaceutical enterprises, the programme is focused on gaining knowledge of the technological processes of manufacturing various dosage forms. The practice involves acquaintance of higher education students with the technological process of manufacturing medicines in pharmacies and pharmaceutical enterprises, quality control, packaging and registration for release; mastering and improving the practical skills and abilities necessary for making independent decisions during specific work in production conditions.

The subject of the practice is to improve the knowledge and skills of manufacturing medicines in an industrial environment.

Together with other pharmaceutical disciplines and social sciences, the educational practice in drug technology plays an important role in shaping the worldview of specialists in the field of pharmacy and in providing them with special technological training for professional activities to supply the population and healthcare facilities with medicines. The practice also develops practical skills in the main stages of formation and development of the pharmaceutical industry and professional activity in Ukraine and abroad, as well as general requirements for the manufacture of medicines.

As a result of studying the discipline, higher education students acquire knowledge of:

- mastery of the requirements of current regulatory documents (State Pharmacopoeia of Ukraine, GPP, guidelines and orders of the Ministry of Health) for the organisation of production activities, for the manufacture of medicines in various dosage forms;
- familiarisation with the organisation of manufacturing of medicinal products in pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice (GMP);
- use in professional activities of regulatory and legislative acts of Ukraine, requirements of Good Pharmacy Practice (GPP) and Good Manufacturing Practice (GMP) for the manufacture of medicines in industrial enterprises;
- development of knowledge of theoretical foundations of manufacturing of different types of dosage forms, stage-by-stage control, ways to improve the technology of dosage forms in industrial conditions;
- studying the influence of storage conditions and type of packaging on the stability of medicinal products; studying industrial equipment, devices and automatic lines.

Prerequisites. The discipline is based on the study of such disciplines of the curriculum as: introduction to pharmacy (basic interdisciplinary interactions in pharmacy, concepts of drug technology and biopharmacy); botany (concepts of systematics, classification, histological structure and chemical composition of medicinal plants); drug technology: ATL; drug technology: PTL; propaedeutic practice in ATL; pharmacognosy.

Purpose of the course. Course objective and its significance for professional activity: The purpose of the training practice in drug technology is to consolidate and deepen theoretical knowledge and practical skills related to the manufacture and quality assessment of dosage forms, as well as the formation of professional competencies.

Postrequisite. The discipline is the basis for the study of the following disciplines: technology of medicinal cosmetics, industrial practice in drug technology, pharmaceutical biotechnology, quality system in pharmacy.

3. Learning outcomes. (A specific result with a focus on practical application that will be achieved and can be verified.

Integrative final programme learning outcomes, the formation of which is facilitated by the Initial Practice in Drug Technology:

- Identification of future professional activity as socially significant for human health. Implementation of professional activity based on general knowledge of the main stages of formation and development of pharmaceutical science and practice in Ukraine and other countries, practical approaches to the organisation of provision of medicines to the population and healthcare facilities, regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.
- Argumentation of decision-making in standard professional situations. Formation of basic knowledge and acquisition of practical skills for further study of professional disciplines.

Programme learning outcomes for the discipline:

- *General competences (GC):*

GC 01: The desire to preserve the environment.

GC 02. Ability to abstract thinking, analysis and synthesis.

GC 03: Knowledge and understanding of the subject area and understanding of professional activities.

GC 04. Ability to adapt and act in a new situation. Ability to take initiative.

GC 06. Skills in the use of information and communication technologies.

GC 07. Ability to choose a communication strategy, ability to work in a team and with experts from other fields of knowledge / types of economic activity.

GC 08. Ability to evaluate and ensure the quality of work performed.

GC 09. Ability to conduct research at the appropriate level.

GC 11. Ability to preserve and enhance the moral, cultural, scientific values and achievements of society based on an understanding of the history and patterns of development of the subject area, its place in the general system of knowledge about nature and society and in the development of society, technology and technology, to use various types and forms of physical activity for active recreation and healthy lifestyle.

- *special (professional, subject) competences (PC)*

PC 01. Ability to store, interpret and apply data necessary for professional activities, research and implementation of innovative projects in the field of pharmacy.

PC 02. Ability to integrate knowledge and solve complex pharmacy problems in broad or multidisciplinary contexts.

PC 04. Ability to use in professional activities the knowledge of regulatory and legal acts of Ukraine and recommendations of good pharmaceutical practices.

PC 05. Ability to demonstrate and apply in practice communication skills, fundamental principles of pharmaceutical ethics and deontology based on moral obligations and values, ethical standards of professional behaviour and responsibility in accordance with the Ethical Code of Pharmacists of Ukraine and WHO guidelines.

PC 06. Ability to clearly and unambiguously communicate own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, including students.

PC 18. Ability to organise and carry out the production activities of pharmacies for the manufacture of medicines in various dosage forms according to prescriptions and orders of medical institutions, including the justification of technology and the choice of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).

PC 19. Ability to organise and participate in the production of medicines in pharmaceutical enterprises, including the selection and justification of the technological process, equipment in accordance with the requirements of Good Manufacturing Practice (GMP) with the appropriate development and execution of the necessary documentation.

PC 22. Ability to organise and carry out quality control of medicinal products in accordance with the requirements of the current State Pharmacopoeia of Ukraine and good practices in pharmacy, to determine methods of sampling for the control of medicinal products and to standardise them in accordance with current requirements, to prevent the distribution of counterfeit medicines.

Program learning outcomes for the discipline:

PLO 01. Apply specialised knowledge and skills in general and specialised disciplines in professional activities.

PLO 02. Critically comprehend scientific and applied problems in the field of pharmacy.

PLO 03. Evaluate and ensure the quality and effectiveness of activities in the field of pharmacy.

PLO 04. To comply with the standards of sanitary and hygienic regime and safety requirements in the performance of professional activities.

PLO 05. Plan and implement professional activities on the basis of regulatory legal acts of Ukraine and recommendations of good pharmaceutical practices.

PLO 07. Demonstrate the ability to independently search, analyse and synthesise information from various sources, including professional literature, patents, databases; evaluate it, in particular, using statistical analysis, as well as apply these results to solve typical and complex specialised tasks of professional activity, including the development and production of medicines.

PLO 08. Develop and make effective decisions on solving complex/complex problems of pharmacy personally and based on the results of joint discussion; formulate goals of own and team activities, taking into account social and industrial interests, overall strategy and existing constraints, determine the best ways to achieve goals.

PLO 15. To formulate, argue, clearly and concretely communicate to specialists and non-specialists, including higher education students, information based on their own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.

PLO 22. Develop technological documentation for the manufacture of medicines, choose a rational technology, manufacture medicines in various dosage forms according to prescriptions and requirements (orders) of healthcare facilities, and prepare them for release.

PLO 23. Carry out pharmaceutical development, substantiate the technology and organise the production of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.

PLO 26. Ensure and carry out quality control of medicinal products of natural and synthetic origin and document its results; issue quality certificates and certificates of analysis in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control

methods (QCM), technological instructions, etc.; take measures to prevent the distribution of low-quality, counterfeit and unregistered medicinal products.

4. Content and logistic of the discipline

Module 1 “Technology of dosage forms for pharmacy and industrial production”	7 semester 75 hours / 2,5 credits	Lectures № Practical classes № Topics for self- study №16
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The course includes 15 topics.

Module 1: Technology of pharmaceutical and industrial dosage forms

Topic 1: Types of regulatory documentation. Requirements of good manufacturing practice for the manufacture of medicines. Requirements for technological process and quality control.

Topic 2: Production of solid dosage forms. Technology of manufacturing powders. Properties of powdered medicinal substances.

Topic 3. Preparation of solid dosage forms. Technology of manufacturing tablets. Assessment of their quality in accordance with the requirements of the normative technical documentation.

Topic 4: Preparation of medicinal products for rectal and vaginal use. Preparation of suppositories.

Topic 5: Production of pharmaceutical solutions. Preparation of aqueous and non-aqueous non-sterile liquid dosage forms.

Topic 6: Preparation of essential oils, aromatic waters.

Topic 7: Production of non-sterile liquid heterogeneous medicinal forms. Technology of manufacturing suspensions. Excipients used in the manufacture of suspensions.

Topic 8: Technology of manufacturing emulsions. Auxiliary substances used in the manufacture of emulsions.

Topic 9: Technology of manufacturing of extraction preparations. Technology of manufacturing tinctures, extracts.

Topic 10: Manufacture of soft drugs. Technology of manufacturing ointments, creams and gels.

Topic 11: Technology of manufacturing of medicines for parenteral use.

Topic 12 Technology of manufacturing of infusion solutions.

Topic 13: Technology of manufacturing of eye and nasal medicines. Excipients used in the manufacturing process.

Topic 14: Technology of manufacturing of plasters and mustard plasters. Excipients used in the manufacture.

Topic 15: Packaging of solid, liquid, soft medicinal products

Independent work involves theoretical substantiation of the main issues of the topic and contributes to the acquisition of practical skills:

- Determine the relationship between the development of drug technology and the general historical development of society.
- Use regulatory, reference, scientific literature to solve professional problems.
- Identify physical, chemical and pharmacological incompatibilities, decide on the possibility of preparing and dispensing medicines taking into account the compatibility of the components of the prescription.
- Check and, if necessary, correct single and daily doses of medicinal substances A and B, and the norms for the release of narcotic and equivalent substances.

- Prepare solid, liquid, soft dosage forms (powders, solutions, mixtures, suspensions, emulsions, infusions, decoctions, injectable solutions, eye drops and lotions, liniments, ointments, suppositories) according to individual prescriptions, taking into account the theoretical foundations of pharmacy drug technology and the requirements of regulatory documents.
- Calculate the number of components of a prescription, the total volume or weight of a medicinal product, and write a written control passport.
- Select the optimal technology option and prepare a medicinal product in accordance with it with a step-by-step quality assessment.
- Evaluate the quality of the prepared drug in accordance with the specifications.
- Comply with storage conditions and packaging to ensure the stability of dosage forms.
- Take into account the impact of pharmaceutical factors (type of dosage form, particle size of medicinal substances, qualitative and quantitative composition of medicinal and excipients, technological processes and devices, etc).
- Identify frequently repeated drug prescriptions and carry out in-pharmacy procurement of medicinal products and semi-finished products according to them.
- Carry out a set of measures to ensure compliance with the sanitary regime in pharmacies and monitor the aseptic preparation of dosage forms.
- Adhere to the deontological principles of relations with the staff of pharmacies, patients and their relatives, and doctors of healthcare facilities.
- Comply with occupational health and safety rules.
- To conduct sanitary and educational work.
- Conduct research to improve dosage forms and their technology.
- To use the legal acts regulating pharmaceutical activities in Ukraine and abroad.
- Use professional knowledge to solve practical situations.
- Analyse professional information, make informed decisions, and acquire up-to-date knowledge.
- Carry out professional activities with continuous updating and integration of knowledge.

The independent work of higher education students involves performing individual tasks and filling out a practice diary, studying topics for independent out-of-class work, writing essays, preparing presentations, tables. The control of mastering the topics of independent out-of-class work is carried out at intermediate control classes at the final control of the discipline.

Individual work includes the study of scientific literature, preparation of reviews on the topics provided for presentation at meetings of the student research group, conducting scientific and practical research, participation in specialised competitions, scientific and practical conferences, and competitions of student research papers.

The thematic plan of independent work, the scope and directions of individual work, methodological recommendations and other necessary educational materials are published on the department's website

The route for obtaining materials: Department of Pharmacy / for students / Full-time education / Pharmacy, industrial pharmacy / 4 course / Educational materials / or through the link <https://www.vnmu.edu.ua/кафедра-фармації#>. Access to the materials is carried out through the student's corporate account s000XXX@vnmu.edu.ua.

5. Forms and methods of monitoring academic performance

Current control in practical studies	Methods: <i>oral or written survey, testing, electronic survey, solving situational problems, conducting laboratory studies, interpreting them and evaluating their results (drawing up a protocol in a workbook)</i>
Control of mastering the thematic section of the discipline at intermediate control lessons	Methods: <i>oral or written survey, electronic testing, situational problem solving, control of practical skills</i>
Final semester control (credit)	According to the Regulation of the Academic process in VNMU named after M.I. Pirogov (link https://www.vnmue.edu.ua/General information)
Learning success diagnostic tools	Theoretical questions, tests, clinically-oriented situational tasks, practical tasks, practical skills demonstration

6. Assessment criteria

Knowledge assessment is carried out in accordance with the Regulations of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmue.edu.ua/General> information)

Continuous assessment	On a four point system of traditional assessments: 5 «excellent», 4 «good», 3 «satisfactory», 2 «unsatisfactory»
Final control of the discipline	<i>Sum of points for pre-examination testing (12-20 points) and oral questioning (38-60 points) (for disciplines included in Step 1,2)</i> Exam grade: 71-80 points - "excellent" 61-70 points - "good" 50-60 points - "satisfactory" Less than 50 points - "unsatisfactory" / did not pass
Discipline assessments:	Current academic assessment - from 72 to 120 points (conversion of the average traditional assessment of practical class on a 120-point scale): 60% of the grade for the discipline Final control - from 50 to 80 points: 40% of the grade for the discipline Individual work - from 1 to 12 points From 122 to 200 points in total.

Discipline Score Scale: National and ECTS

The sum of grades for all types of educational activities	Score ECTS	Score on a national scale	
		For exam, course project (work), practice	for credit test
180-200	A	excellent	credited
170-179,99	B		

160-169,99	C	good	
141-159,99	D	satisfactory	
122-140,99	E	satisfactory	
119-61	FX	unsatisfactory with the possibility of reassembly	is not credited with the possibility of reassembling
1-60	F	unsatisfactory with a mandatory reexamination of discipline	is not credited with mandatory reexamination of discipline

7. Policy of discipline / course

The student has the right to receive high-quality educational services, access to contemporary scientific and educational information, qualified advisory assistance during the study of discipline and mastering practical skills. The policy of the department during the providing of educational services is a student-centered, based on normative documents of the Ministry of Education and the Ministry of Health of Ukraine, the Statute of the University and the Procedure for the Providing of Educational Services regulated by the main principles of the organization of the educational process in VNMU named after M.I.Pirogov and the principles of academic integrity (link <https://www.vnmue.edu.ua/General> information).

Adherence to the rules of VNMU, safety techniques in practical classes.

Safety instruction is given at the first practical lesson by the teacher. The briefing is registered in the Safety Briefing Journal. Applicant for higher education who has not been instructed is not allowed to practical class. In case of announcement of the "Air Alert" signal or other warning signals, the teacher stops classes, informs higher education students about the need to go to a civil defence shelter and stay there until the signal is cancelled. The teacher informs the students about further actions after the signal is cancelled: to continue the class or to recommend to revise the material on their own with a subsequent survey at the next lesson (Order No. 505 of 30.08.2023).

Requirements for preparation for practical classes. Applicant for higher education should be present at the practical lesson on time, theoretically prepared according to the topic. Applicant for higher education should come to class on time, without lateness. Applicant for higher education who is late is not allowed to study and must rework it in the prescribed manner.

In practical classes, the applicant for higher education must be dressed in a work uniform. Applicants for higher education who do not have a work uniform are not allowed to study.

The applicant for higher education must follow the rules of safety in practical classes and during the stay in the department.

When discussing theoretical issues, students should demonstrate tolerance, courtesy and respect for their colleagues and the teacher; when performing practical tasks, the workplace should be kept in order and cleaned after the practical work.

Usage of mobile phones and other electronic devices. The use of mobile phones and other electronic devices in the classroom is allowed only on the instructions of the teacher.

Academic integrity. When studying the discipline, the student must be guided by the Code of Academic Integrity and Corporate Ethics of VNMU named after M.I. Pirogov (link : <https://www.vnmue.edu.ua/General> information)/ Code of Academic Integrity). In case of violation of the norms of academic integrity during the current and final controls student receives a grade of "2" and must work it out to his teacher in the prescribed manner within two weeks after receiving an unsatisfactory assessment).

Academic integrity. During the study of the discipline the Applicants for higher education must be guided by the Code of Academic Integrity of VNMU named after MI Pirogov. In case of violation of the norms of academic integrity during the current and final controls, the Applicants

for higher education receives a grade of "2" and must work it in the prescribed manner for two weeks.

Missed classes. Missed classes are working out in the manner prescribed by Regulations of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmue.edu.ua/General> information) at the time of work out schedule (published on the website of the department <https://www.vnmue.edu.ua/> department of pharmacy #) to the teacher on duty.

The procedure for admission to the discipline final control is given in the Regulations of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmue.edu.ua/General> information). To the final control allowed students who do not have missed practical classes and lectures and received an average traditional grade of at least "3".

Additional points. Individual points in the discipline (from 1 to 12) that student can receive for individual work, the amount of which is published on the website of the department in the educational methodical materials of the discipline, the number of points is determined by the results of IRS according to Regulation of the Academic process in VNMU named after M.I. Pirogov (link <https://www.vnmue.edu.ua/General> information).

Conflict resolution. In case of misunderstandings and complaints to the teacher because of the quality of educational services, knowledge assessment and other conflict situations, students should submit his / her claims to the teacher. If the issue is not resolved, the student has the right to apply to the head of the department according to Complaints Consideration Procedure in VNMU named after M.I. Pirogov (link <https://www.vnmue.edu.ua/General> information)

Politics in terms of remote learning. Distance learning regulated by the Regulations of the elements of remote learning in VNMU named after Pirogov M.I. (<https://www.vnmue.edu.ua/General> information). The main training platforms for studying are Microsoft Team and Google Meets. Practical classes and lectures, exercises and consultations during distance learning is published on the website of the department (<https://www.vnmue.edu.ua/> Department of of pharmacy / to Students or <https://www.vnmue.edu.ua/Department of Microbiology / News>).

Feedback from the teacher is provided through the distance learning platform (Microsoft Teams), messengers or e-mail (at the teacher's discretion) during working hours.

Higher education students have the right to receive quality educational services, access to up-to-date scientific and educational information, qualified advisory assistance in the study of the discipline and mastering practical skills. The department's policy in providing educational services is student-centred, based on the regulations of the Ministry of Education and the Ministry of Health of Ukraine, the university's charter and the procedure for providing educational services, regulated by the main provisions of the educational process at the Pirogov National Medical University and the principles of academic integrity.

8. Educational resources

The educational and methodological support of the discipline is published on the website of the department (<https://www.vnmue.edu.ua/> department ____pharmacy_____/ Student). Consultations are held twice a week according to the consultation schedule.

9. The schedule and distribution of groups by teachers is published on the website of the department (<https://www.vnmue.edu.ua/> department ____pharmacy_____/ Student).

10. Questions for intermediate and final controls of the discipline are published on the website of the department (<https://www.vnmue.edu.ua/> department ____pharmacy_____/ Student).

Recommended literature

1. The practical course on Industrial Technology of Medicines for students of specialty "Pharmacy"/ Ed. By Doctor of Pharmacy, professor Ruban H.A. - Kharkov: NUPh. 2013.- 298p.
2. Industrial Drug Technology: Tutorial for laboratory classes for students of specialty "Pharmacy"/ Yu.V. Yudina, Yu. V. Shmyrova, S.V. Stepanenko, Ie.V. Gladukh, V.I. Chyieshov, A.A. Sichkar, Ye.A. Bezrukaviy, O.S. Kukhtenko. - Kharkov: NUPh: Original, 2012.- 254p.
3. The Theory and Practical Book of Industrial Pharmacy - I / Ketan B. Patil, Paresh A. Patil, Sandip S. Kshirsagar, Narendra B. Patil, 2020. 207p.
4. Textbook of industrial pharmacy II Mrs. Shweta S. Gedam, Shivraj P. Jadhav, Eknath D. Ahire. - Pritam Publications, 2022.- 202p.
5. A Textbook of Industrial Pharmacy I / Dr. Prashant Pingale.- Everest Publishing House, 2022.-485p.
6. INDUSTRIAL PHARMACY - II / Dr. Ashok A. Hajare.- Nirali Prakashan, 2022.-281p.

The syllabus of the discipline " Proceeding practice on drug technology" was discussed and approved at the meeting of the department pharmacy (record №_1_, dated " 30 " _08_ 2024)

Responsible for the academic
discipline

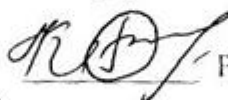
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Ass. prof. of HEI Tetiana VOITENKO

Head of the department

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Prof. of HEI Olena KRYVOVIAZ